

**APPEAL BRIEF UNDER 37 C.F.R. § 41.37**

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**S/N 10/756,897**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellant:	James O. Gilkerson et al.	Examiner:	Scott Getzow
Serial No.:	10/756,897	Group Art Unit:	3762
Filed:	January 14, 2004	Docket No.:	279.214US3
Customer No.:	45458	Confirmation No.:	3622
Title:	IMPLANTABLE DEFIBRILLATORS WITH PROGRAMMABLE CROSS-CHAMBER BLANKING		

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**APPEAL BRIEF UNDER 37 CFR § 41.37**

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Alexandria, VA 22313-1450

The Appeal Brief is presented in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed on February 14, 2011 and further in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on December 22, 2010, from the Final Rejection of claims 25 – 33 and 36 – 45 of the above-identified application, as set forth in the Office Action mailed on July 26, 2010.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of \$540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of the pending claims.

## **1. REAL PARTY IN INTEREST**

The real party in interest of the above-captioned patent application is the assignee, Cardiac Pacemakers, Inc., as evidenced by the Assignment recorded on November 9, 1999, Reel 010370, and Frames 0264-0267. Cardiac Pacemakers, Inc. is a subsidiary of Boston Scientific Corporation.

## **2. RELATED APPEALS AND INTERFERENCES**

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

### **3. STATUS OF THE CLAIMS**

The present application was filed on January 14, 2004, with claims 1 – 5. In a Preliminary Amendment filed on July 16, 2004, Appellant canceled claims 3 – 5 and added claims 6 – 10. In response to a Non-Final Office Action mailed on June 15, 2006, Appellant added claims 11 – 23. A Non-Final Office Action was mailed on June 25, 2007. A Request for Continued Examination (RCE) was filed in response to the Final Office Action mailed January 16, 2008.

A Non-Final Office Action was mailed on June 9, 2008. In response to a Non-Final Office Action mailed on February 27, 2009, Appellant added claim 24. A Request for Continued Examination (RCE) was filed in response to the Final Office Action mailed September 22, 2009 wherein Appellants canceled claims 1 – 24 and added claims 25 – 47.

In response to a Non-Final Office Action mailed on January 15, 2010, Appellant canceled claims 34 – 35 and 46 – 47. A Final Office Action (hereinafter “the Final Office Action”) was mailed on July 26, 2010. Claims 25 – 33 and 36 – 45 stand twice rejected, remain pending, and are the subject of the present Appeal.

#### **4. STATUS OF AMENDMENTS**

No amendments have been made subsequent to the Final Office Action dated July 26, 2010.

## **5. SUMMARY OF CLAIMED SUBJECT MATTER**

Aspects of the present claimed subject matter include, but are not limited to, implantable defibrillators with programmable cross-chamber blanking.

### **INDEPENDENT CLAIM 25**

25. A system, comprising:

an implantable monitoring circuit [e.g., FIG. 1 at 140, p. 4, lines 10 – 12] comprising:

a first sensing input configured to receive information indicative of a ventricular electrical signal corresponding to a ventricular event [e.g., FIG. 1 at 150, p. 4, lines 24 – 28, p. 5, lines 4 – 11];

a second sensing input configured to receive information indicative of an atrial electrical signal corresponding to an atrial event [e.g., FIG. 1 at 150, p. 4, lines 24 – 28, p. 5, lines 4 – 11]; and

a memory circuit configured to store an adjustable blanking interval [e.g., FIG. 1 at 144, p. 4, lines 13 – 18] ;

an implantable therapy circuit configured to provide electrical energy to be therapeutically delivered to a heart as directed by the implantable monitoring circuit [e.g., FIG. 1 at 160, p. 5, lines 12 – 24];

wherein the implantable monitoring circuit is configured to inhibit sensing, for a duration corresponding to the adjustable blanking interval, of at least one of (1) the atrial electrical signal when the information indicative of the ventricular electrical signal received by the first sensing input includes a ventricular event [e.g., FIG. 2 at 224, p. 7, lines 6 – 12], or (2) the ventricular electrical signal when the information indicative of the atrial electrical signal received by the second sensing input includes an atrial event [e.g., FIG. 2 at 224, p. 7, lines 6 – 12];

wherein the implantable monitoring circuit is configured to receive the information indicative of at least one of (1) the atrial electrical signal, or (2) the ventricular electrical signal, during a noise window interval [e.g., p. 7, lines 23 – 25], the noise window interval derived from a difference between a preset refractory period and the adjustable blanking interval [e.g., FIG. 3, p. 6, lines 17 – 28]; and

wherein the implantable monitoring circuit is configured to ignore the information received during the noise window interval, for at least the purpose of directing the implantable therapy circuit to provide pacing therapy [e.g., p. 7, lines 23 – 25].

### INDEPENDENT CLAIM 37

37. A memory circuit within an implantable device [e.g., FIG. 1 at 144, p. 4, lines 13 – 18], the memory circuit comprising instructions for operating the implantable device [e.g., FIG. 1 at 144, p. 4, lines 14 – 16], the instructions when performed by a processor within the implantable device causing the implantable device to:

store an adjustable blanking interval [e.g., FIG. 1 at 144, p. 4, lines 13 – 18];

receive information indicative of a ventricular electrical signal corresponding to a ventricular event [e.g., FIG. 1 at 150, p. 4, lines 24 – 28, p. 5, lines 4 – 11];

receive information indicative of an atrial electrical signal corresponding to an atrial event [e.g., FIG. 1 at 150, p. 4, lines 24 – 28, p. 5, lines 4 – 11];

therapeutically deliver electrical energy to a heart using the information indicative of at least one of the ventricular electrical signal or the atrial electrical signal [e.g., FIG. 1 at 160, p. 5, lines 12 – 24]; and

inhibit sensing, for a duration corresponding to the adjustable blanking interval, of at least one of (1) the atrial electrical signal when the information indicative of the ventricular electrical signal includes the ventricular event [e.g., FIG. 2 at 224, p. 7, lines 6 – 12], or (2) the ventricular electrical signal when the information indicative of the atrial electrical signal includes the atrial event [e.g., FIG. 2 at 224, p. 7, lines 6 – 12];

wherein the instructions causing the implantable device to receive the information indicative of the ventricular electrical signal or the atrial electrical signal include causing the implantable device to ignore, for at least the purpose of therapeutically delivering pacing therapy to the heart, for a duration specified by the first adjustable blanking interval, the information received during a noise window interval [e.g., p. 7, lines 23 – 25], the noise window interval derived from a difference between a present refractory period and the adjustable blanking interval [e.g., FIG. 3, p. 6, lines 17 – 28].



This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellants refer to each of the appended claims and its legal equivalents for a complete statement of the invention.

**6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. Whether claims 25 – 33 and 36 were properly rejected under 35 U.S.C. 102(b) over Levine et al. (U.S. Patent No. 5,776,167; hereinafter “Levine”).
2. Whether claims 37 – 45 were properly rejected under 35 U.S.C. 103(a) over Levine.
3. Whether claims 25 – 33 and 36 – 45 were properly rejected under 35 U.S.C. 103(a) over Lu (U.S. Patent No. 5,591,214) in view of Levine.

## **7. ARGUMENT**

### ***A) The Applicable Law***

#### **A.1 Standard of Review**

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument. If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.”<sup>1</sup>

#### **A.2 Novelty under 35 U.S.C. §102**

In order to anticipate a claim, a reference must teach all limitations, arranged or combined in the same way as recited in Applicants’ claim. The Court of Appeals for the Federal Circuit has held that:

[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.<sup>2</sup>

#### **A.3 Obviousness under 35 U.S.C. § 103**

Obviousness requires that the Examiner meet his or her burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness.<sup>3</sup> As discussed by the U.S. Supreme Court in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), the determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence.<sup>4</sup> The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues set

<sup>1</sup> *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) (citations omitted); see *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

<sup>2</sup> *Net MoneyIn, Inc. v. Verisign, Inc.*, No. 2007-1565 at 17. (Fed. Cir. Oct. 20, 2008)

<sup>3</sup> *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

<sup>4</sup> See *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37, 75 USPQ2d 1051 (Fed. Cir. 2005).

forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

In combining prior art references to construct a *prima facie* case, the Examiner must show some objective evidence in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant portions of the references.<sup>5</sup> However, the level of skill is generally that of the person who follows the conventional wisdom in the art.<sup>6</sup> An invention can be obvious even though the reason to combine prior art teachings is not found in a specific reference.<sup>7</sup> But the requirement of some reason to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Lee*,<sup>8</sup> which notes that the reason must be supported by some evidence in the record.

The *KSR* Court merely rejected a rigid application of any “teaching, suggestion, motivation” test; it recognized that a more flexible conception of the test is entirely consistent with the *Graham* analysis.<sup>9</sup> The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention.<sup>10</sup> References must be considered in their entirety, including parts that teach away from the claims.<sup>11</sup> The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.<sup>12</sup>

Notably, the *KSR* Court affirmed that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”<sup>13</sup> The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103,

<sup>5</sup> *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

<sup>6</sup> *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454, 227 USPQ 293, 298 (Fed. Cir. 1985).

<sup>7</sup> *See In re Oetiker*, 977 F.2d 1443, 1448, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992).

<sup>8</sup> *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

<sup>9</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401, 127 S.Ct. 1727, 1731 (2007).

<sup>10</sup> *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).

<sup>11</sup> *See M.P.E.P.* § 2141.02.

<sup>12</sup> *See generally In re Mills*, 916 F.2d 680, 16 USPQ2d 1430, 1432-1433 (Fed. Cir. 1990); *M.P.E.P.* § 2143.01.

<sup>13</sup> *See In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1335-1336 (CA Fed. 2006) (cited with approval in *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41 (2007)).

recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art.<sup>14</sup> Moreover, when a reference teaches away from a claimed invention, this fact highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art.<sup>15</sup> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.<sup>16</sup> The CCPA has also noted that “[t]he court must be ever alert not to read obviousness into an invention on the basis of the applicant’s own statements; that is, we must view the prior art without reading into that art appellant’s teachings.”<sup>17</sup> Thus, these principles have not been changed by the ruling in *KSR*.

**B) The References**

**Levine:** Levine discloses methods and apparatus for alleviating the effects of crosstalk in an implantable stimulation device.<sup>18</sup>

**Lu:** Lu discloses a pacemaker with an automatic blanking period function.<sup>19</sup>

**C) Discussion of the Rejections**

**C.1. The rejection of claims 25 – 33 and 36 under 35 U.S.C. 102(b) over Levine Concerning Claims 25 – 33 and 36:**

Appellant respectfully submits that the Final Office Action has clearly erred in rejecting claims 25 – 33 and 36 because no *prima facie* case of anticipation has been properly established. Levine fails to disclose or suggest all the recitations of claims 25 – 33 and 36 and the Office Action fails to provide reasoning or facts sufficient to fill the gaps between Levine and the presently-pending claims.

*Levine fails to disclose all the recitations of claims 25 – 33 and 36*

<sup>14</sup> See *In re Bond*, 910 F.2d 831,834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh’g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990).

<sup>15</sup> *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 1990 WL 10072072, 15 USPQ2d 1704, 1713 (Tex. 1990).

<sup>16</sup> See generally *In re Ratti*, 270 F.2d 810, 123 USPQ 349, 352 (CCPA 1959).

<sup>17</sup> *In re Spomobile*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).

<sup>18</sup> See Levine at Abstract.

<sup>19</sup> See Lu at Title.

Levine mentions a:

blanking interval [] made up of an initial absolute blanking interval [] during which the sense amplifiers 20 and 30 are preferably disabled, followed by a retriggerable relative blanking interval [] during which signals may be sensed, but are presumed to be crosstalk. If a signal is sensed during a first relative blanking interval, the pacemaker 10 automatically restarts another relative blanking interval. When a complete relative blanking interval passes without any sensed signal, blanking is terminated.<sup>20</sup>

In contrast, the present claims similarly recite or incorporate an *adjustable* blanking interval during which “the implantable monitoring circuit is configured to inhibit sensing, for a duration corresponding to the adjustable blanking interval,” and a noise window, during which the “implantable monitoring circuit is configured to ignore the information received during [the] noise window interval,” the noise window interval being “derived from a difference between a preset refractory period and the adjustable blanking interval.”

For example, Levine apparently fails to teach, disclose, or even suggest an *adjustable* blanking interval where “the implantable monitoring circuit is configured to inhibit sensing, for a duration corresponding to the adjustable blanking interval,” as recited in claim 25. The total blanking interval mentioned by Levine “is made up of an initial absolute blanking interval . . . followed by a retriggerable relative blanking interval.”<sup>21</sup> Even if Levine’s initial absolute blanking interval could somehow arguably be functionally similar in blanking behavior to the *adjustable* blanking window of the present claims, the *duration* of Levine’s initial absolute blanking interval is not *adjustable*.

The Office Action asserts that the relative blanking interval of Levine “can be considered the noise window interval.”<sup>22</sup> This assertion is irrelevant, as Levine still fails to disclose that its “relative blanking interval” is “derived from a difference between a preset refractory period and [an] *adjustable* blanking interval.” In fact, the Office Action makes no attempt to explain how such a difference is taught, disclosed, or even suggested by Levine. In particular, Levine mentions that “[i]f a signal is sensed during a first relative blanking interval, the pacemaker 10 automatically restarts another relative blanking interval. When a complete relative blanking

<sup>20</sup> Levine, col. 7, lines 31 – 39.

<sup>21</sup> Levine, col. 7, lines 31 – 34.

<sup>22</sup> See Office Action of July 26, 2010, p. 2, § 1 (hereinafter “Office Action”).

interval passes without any sensed signal, blanking is terminated.”<sup>23</sup> Thus, the total of all the relative blanking intervals of Levine appears to depend on how long it takes for a single complete relative blanking interval to pass without any sensed signal,<sup>24</sup> and not “a difference between a preset refractory period and the adjustable blanking interval.” As a result, the total of all the relative blanking intervals are clearly not the same as a noise window that is “derived from a difference between a preset refractory period and the adjustable blanking interval,” as recited or incorporated in the present claims.

Levine also fails to mention inhibiting ventricular sensing more generally in response to an atrial event as recited in claims 25 and 37. For example, such an atrial event as presently recited could include either a pacing event or an intrinsic sensed event, unlike Levine.<sup>25</sup>

The Office Action fails to provide reasoning or facts to fill the gaps between Levine and the present claims. The Office Action’s rejection of claim 25 is conclusory and vague as to where the specific recitations of claim 25 are somehow disclosed or taught by Levine. The Federal Circuit recently stated:

The Patent and Trademark Office (“PTO”) satisfies its initial burden of production by “adequately explain[ing] the shortcomings it perceives so that the applicant is properly notified and able to respond.” In other words, the PTO carries its procedural burden of establishing a *prima facie* case when its rejection satisfies 35 U.S.C. § 132, in “notify[ing] the applicant . . . [by] stating the reasons for [its] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application.” 35 U.S.C. § 132. That section “is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection.”<sup>26</sup>

Appellant respectfully submits that the present § 102 rejection is an example of a rejection that is “so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection.” For example, the Office Action fails to point out where Levine discloses the adjustable blanking interval or how the relative blanking interval of Levine meets the claimed recitation of a noise window. Additionally, the Office Action asserts that “Re the dependent claims, all of the claimed structure is considered to be encompassed by the device of Levine. For

<sup>23</sup> Levine, col. 7, lines 36 – 40.

<sup>24</sup> Levine, col. 7, lines 38 – 40.

<sup>25</sup> See Levine at FIG. 5, as cited in the Office Action (mentioning applying atrial stimulation and disabling a ventricular sense amplifier during an absolute blanking interval).

<sup>26</sup> *In re Jung*, 2010 – 1019 (Fed. Cir. March 28, 2011) (citations omitted).

example, the blanking intervals can be programmed by a physician . . . Further, first and second leads are implicit in figure 1 of Levine.”<sup>27</sup> Such conclusory and vague statements cannot support a *prima facie* case of anticipation because Appellant is left with virtually no reasoning or factual assertions to challenge the basis of the rejection.

In sum, the § 102 rejection of independent claim 25 and its dependent claims is clearly erroneous because no *prima facie* case of anticipation has been shown. Levine fails to disclose *each and every element* of the present claims, and the reasoning of the Office Action fails to bridge the gaps between Levine and the present claims. Appellant respectfully requests reversal.

### **C.2. The rejection of claims 37 – 45 under 35 U.S.C. 103(a) over Levine**

#### **Concerning Claims 37 – 45:**

Appellant also respectfully submits that the § 103(a) rejection over Levine is clearly erroneous and should be reversed for reasons similar to those discussed above in relation to the § 102 rejection. The § 103 rejection also appears to be conclusory and is almost entirely devoid of supporting factual assertions.<sup>28</sup> The Office Action asserts that “[i]n addition to the comments made above, it is considered obvious to have a memory circuit that contains instructions for all of the steps outlined in claim 37.”<sup>29</sup> The Office Action also asserts that “such programming for a pacemaker is common in the art, since most IMDs are microprocessor based, and further no unexpected result would come from such circuit containing instructions as claimed.”<sup>30</sup> Appellant respectfully submits that the Office Action has failed to articulate some rational underpinning supporting the § 103 rejection of claims 37 – 45, because the Office Action entirely omits any discussion of the majority of the recitations of claim 37, other than the memory circuit. Accordingly, Appellant respectfully requests reversal of this clearly erroneous rejection.

### **C.3. The rejection of claims 25 – 33 and 36 – 45 under 35 U.S.C. 103(a) over Lu (U.S. Patent No. 5,591,214) in view of Levine.**

#### **Concerning claims 25 – 33, 36 – 45:**

Appellant respectfully submits that no *prima facie* case of obviousness has been shown, for reasons similar to those discussed above with respect to the erroneous § 102 rejection, and

<sup>27</sup> See Office Action, p. 2, § 1.

<sup>28</sup> See M.P.E.P. § 2132, “II. The Basic Factual Inquiries of Graham v. John Deere Co.”

<sup>29</sup> Office Action at p. 2, § 2.

<sup>30</sup> Office Action at p.3 § 2.



with respect to the § 103 rejection over Levine, because Lu, Levine and/or the reasoning of the Office Action fail to teach or even suggest the subject matter of claims 25, 37, or their respective dependent claims. Also, the Office Action has failed to meet its obligations to clearly articulate the reasoning for the rejection.

In the rejection, the Office Action first asserts that: “[f]or a discussion of Lu, see previous office action. As mentioned above, Levine teaches the use of a noise window interval. To use such with the device of Lu would have been obvious in that such a combination would yield predictable results, and further the effects of crosstalk would be alleviated, as mentioned in the abstract of Levine.”<sup>31</sup> As already mentioned, Levine fails to disclose the claimed noise window, where the noise window is “derived from a difference between a preset refractory period and the adjustable blanking window.” Lu does not cure this deficiency as Lu does not appear to mention a noise window so configured. As such, the Office Action fails to establish a *prima facie* case of obviousness because the references fail to disclose or even suggest all the subject matter of claims 25-33, or 36-45.

The Office Action provides a conclusory assertion of obviousness and refers Appellant to a previous Office Action, instead of providing factual assertions to bridge the substantial gaps between the references and the present claims. The previous Office Action (Non-Final rejection mailed on 1/15/2010) rejected a prior version of the claims under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) over Lu. Subsequently, claim 25 was amended to provide that:

the implantable monitoring circuit is configured to receive the information indicative of at least one of (1) the atrial electrical signal, or (2) the ventricular electrical signal, during a noise window interval, the noise window interval derived from a difference between a preset refractory period and the adjustable blanking interval; and wherein the implantable monitoring circuit is configured to ignore the information received during the noise window interval, for at least the purpose of directing the implantable therapy circuit to provide pacing therapy.

Claim 37 was similarly amended. Because the previous Office Action (i.e., the Non-Final Office Action mailed on 1/15/2010) did not address the amended version of the claims, the reasoning of the previous Office Action does not remedy the deficiencies of the current Office Action. The presently-claimed noise window is not disclosed, taught, or even suggested by the references and/or the reasoning of the Office Action. In addition, the Office Action fails to articulate an

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<sup>31</sup> Office Action at p. 3, § 3.

objective motivation for combining Lu with Levine, nor, even if somehow possible, how such a combination could be made, or that such a combination would produce a reasonable likelihood of success.

The KSR Court affirmed that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”<sup>32</sup> The Federal Circuit has explicitly stated that:

The foundation of the principle of judicial deference to the rulings of agency tribunals is that the tribunal has specialized knowledge and expertise, such that when reasoned findings are made, a reviewing court may confidently defer to the agency's application of its knowledge in its area of expertise. Reasoned findings are critical to the performance of agency functions and judicial reliance on agency competence. See *Baltimore and Ohio R. R. Co. v. Aberdeen & Rockfish R. R. Co.*, 393 U.S. 87, 91-92 (1968) (absent reasoned findings based on substantial evidence effective review would become lost “in the haze of so-called expertise”). The “common knowledge and common sense” on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697, that “deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is ‘basic knowledge’ or ‘common sense.’” The Board's findings must extend to all material facts and must be documented on the record, lest the “haze of so-called expertise” acquire insulation from accountability. “Common knowledge and common sense,” even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority. See *Allentown Mack*, 522 U.S. at 376 (“Because reasoned decision-making demands it, and because the systemic consequences of any other approach are unacceptable, the Board must be required to apply in fact the clearly understood legal standards that it enunciates in principle . . . .”)<sup>33</sup>

In view of the guidance cited above, the conclusory statements of the Office Action are insufficient to support a *prima facie* case of obviousness at least because the rejection: fails to cite references that disclose or suggest each and every element of the claims, fails to provide sufficient factual assertions to bridge these substantial gaps in the references, fails to describe

<sup>32</sup> See *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1335-1336 (CA Fed. 2006) (cited with approval in *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41 (2007)).

<sup>33</sup> *In re Lee* 277 F.3d 1338, 1345 (Fed. Cir. 2002) .

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how the proposed combination would work, and whether such a combination would have a reasonable likelihood of success, and fails to provide a motivation to attempt such a combination.

In sum, Appellant respectfully requests reversal of the clearly erroneous rejections of claims 25, 37, and their respective dependent claims because Lu and Levine fail to disclose the subject matter of claims 25, 37, or their respective dependent claims. The Office Action fails to remedy such deficiencies with facts sufficient to fill the substantial gaps between Lu, Levine, and the subject matter of the present claims, and instead provides conclusory assertions of obviousness. The Office Action also fails to articulate how Lu and Levine could somehow be combined, and fails to provide an objective motivation for such a combination, assuming that such a combination were even somehow possible.

**SUMMARY**

For the reasons argued above, claims 25 – 33 and 36 were not properly rejected under 35 U.S.C. 102(b) as being unpatentable over Levine; claims 37 – 45 were not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Levine; and claims 25 – 33 and 36 – 45 were not properly rejected under 35 U.S.C. 103(a) as unpatentable over Lu (U.S. Patent No. 5,591,214) in view of Levine.

It is respectfully submitted that the art cited does not render the claims anticipated or obvious and that the claims are patentable over the cited art. Reversal of the rejections and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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## **8. CLAIMS APPENDIX**

25. A system, comprising:

an implantable monitoring circuit comprising:

a first sensing input configured to receive information indicative of a ventricular electrical signal corresponding to a ventricular event;

a second sensing input configured to receive information indicative of an atrial electrical signal corresponding to an atrial event; and

a memory circuit configured to store an adjustable blanking interval;

an implantable therapy circuit configured to provide electrical energy to be therapeutically delivered to a heart as directed by the implantable monitoring circuit;

wherein the implantable monitoring circuit is configured to inhibit sensing, for a duration corresponding to the adjustable blanking interval, of at least one of (1) the atrial electrical signal when the information indicative of the ventricular electrical signal received by the first sensing input includes a ventricular event, or (2) the ventricular electrical signal when the information indicative of the atrial electrical signal received by the second sensing input includes an atrial event;

wherein the implantable monitoring circuit is configured to receive the information indicative of at least one of (1) the atrial electrical signal, or (2) the ventricular electrical signal, during a noise window interval, the noise window interval derived from a difference between a preset refractory period and the adjustable blanking interval; and

wherein the implantable monitoring circuit is configured to ignore the information received during the noise window interval, for at least the purpose of directing the implantable therapy circuit to provide pacing therapy.

26. The system of claim 25, wherein the implantable monitoring circuit is configured to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial electrical signal when the information indicative of the ventricular electrical signal includes an intrinsic ventricular event.

27. The system of claim 25, wherein the implantable monitoring circuit is configured to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial electrical signal when the information indicative of the ventricular electrical signal includes a paced ventricular event.

28. The system of claim 25 wherein the implantable monitoring circuit is configured to disable the second sensing input, for a duration specified by the adjustable blanking interval, when the information indicative of the ventricular electrical signal includes the ventricular event; and

wherein the implantable monitoring circuit is configured to enable the second sensing input during the noise window interval, while ignoring the information received by the second sensing input, during the noise window interval, for the purpose of directing the implantable therapy circuit to provide pacing therapy.

29. The system of claim 25, wherein the implantable monitoring circuit is configured to inhibit sensing for a duration specified by the adjustable blanking interval, of the ventricular electrical signal when the information indicative of the atrial electrical signal includes an intrinsic atrial event.

30. The system of claim 25, wherein the implantable monitoring circuit is configured to inhibit sensing, for a duration specified by the adjustable blanking interval, of the ventricular electrical signal when the information indicative of the atrial electrical signal includes a paced atrial event.

31. The system of claim 29, wherein the implantable monitoring circuit is configured to disable the first sensing input, for a duration specified by the adjustable blanking interval, when the information indicative of the atrial electrical signal includes the atrial event; and

wherein the implantable monitoring circuit is configured to enable the first sensing input during the noise window interval, while ignoring the information received by the first sensing

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input, during the noise window interval, for the purpose of directing the implantable therapy circuit to provide pacing therapy.

32. The system of claim 25, wherein the implantable monitoring circuit is configured to disable sensing, for a duration specified by a first adjustable blanking interval, of the ventricular electrical signal when the information indicative of the atrial electrical signal includes an intrinsic atrial event; and

wherein the implantable monitoring circuit is configured to disable sensing, for a duration specified by a second adjustable blanking interval, of the atrial electrical signal when the information indicative of the ventricular electrical signal includes an intrinsic ventricular event.

33. The system of claim 25, further comprising:

an external interface device comprising a user input configured to receive the adjustable blanking interval from a user;

wherein the external interface device is configured to transmit the adjustable blanking interval to the implantable monitoring circuit; and

wherein the implantable monitoring circuit is configured to store the received adjustable blanking interval in the memory circuit.

36. The system of claim 25, further comprising:

a first lead coupled to the first sensing input and configured to sense the ventricular electrical signal;

a second lead coupled to the second sensing input and configured to sense the atrial electrical signal; and

wherein the implantable therapy circuit is coupled to at least one of the first or second leads.

37. A memory circuit within an implantable device, the memory circuit comprising instructions for operating the implantable device, the instructions when performed by a processor within the implantable device causing the implantable device to:

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store an adjustable blanking interval;

receive information indicative of a ventricular electrical signal corresponding to a ventricular event;

receive information indicative of an atrial electrical signal corresponding to an atrial event;

therapeutically deliver electrical energy to a heart using the information indicative of at least one of the ventricular electrical signal or the atrial electrical signal; and

inhibit sensing, for a duration corresponding to the adjustable blanking interval, of at least one of (1) the atrial electrical signal when the information indicative of the ventricular electrical signal includes the ventricular event, or (2) the ventricular electrical signal when the information indicative of the atrial electrical signal includes the atrial event;

wherein the instructions causing the implantable device to receive the information indicative of the ventricular electrical signal or the atrial electrical signal include causing the implantable device to ignore, for at least the purpose of therapeutically delivering pacing therapy to the heart, for a duration specified by the first adjustable blanking interval, the information received during a noise window interval, the noise window interval derived from a difference between a present refractory period and the adjustable blanking interval.

38. The memory circuit of claim 37, wherein the instructions causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial or the ventricular electrical signal include causing the implantable device inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial electrical signal when the information indicative of the ventricular electrical signal includes an intrinsic ventricular event.

39. The memory circuit of claim 37, wherein the instructions causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial electrical signal include causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial electrical signal when the information indicative of the ventricular electrical signal includes a paced ventricular event.



40. The memory circuit of claim 37, wherein the instructions causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial electrical signal include causing the implantable device to disable a sensing input from receiving information indicative of the atrial electrical signal, for a duration specified by the adjustable blanking interval, when the information indicative of the ventricular electrical signal includes the ventricular event; and

wherein the instructions include causing the implantable device to enable the sensing input to receive information indicative of the atrial electrical signal, during the noise window interval, while causing the implantable device to ignore the information received by the sensing input, during the noise window interval, for the purpose of therapeutically delivering pacing therapy to the heart.

41. The memory circuit of claim 37, wherein the instructions causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the atrial or the ventricular electrical signal include causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the ventricular electrical signal when the information indicative of the atrial electrical signal includes an intrinsic atrial event.

42. The memory circuit of claim 37, wherein the instructions causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the ventricular signals include causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the ventricular electrical signal, when the information indicative of the atrial electrical signal includes a paced atrial event.

43. The memory circuit of claim 37, wherein the instructions causing the implantable device to inhibit sensing, for a duration specified by the adjustable blanking interval, of the ventricular electrical signal include causing the implantable device to disable a sensing input from receiving information indicative of the ventricular electrical signal, for a duration specified by the adjustable blanking interval, when the information indicative of the atrial electrical signal includes the intrinsic atrial event; and

wherein the instructions include causing the implantable device to enable the sensing input to receive information indicative of the ventricular electrical signal, during the noise window interval, while causing the implantable device to ignore the information received by the sensing input, during the noise window interval, for the purpose of therapeutically delivering pacing therapy to the heart.

44. The memory circuit of claim 37, wherein the instructions include causing the implantable device to store a first adjustable blanking interval and a second adjustable blanking interval; and wherein the instructions causing the implantable device to inhibit sensing of the atrial or ventricular signals include causing the medical device to:

disable sensing, for a duration specified by the first adjustable blanking interval, of the ventricular electrical signal when the information indicative of the atrial electrical signal includes an intrinsic atrial event; and

disable sensing, for a duration specified by the second adjustable blanking interval, of the atrial electrical signal when the information indicative of the ventricular electrical signal includes an intrinsic ventricular event.

45. The memory circuit of claim 37, comprising instructions causing the implantable device to receive the adjustable blanking interval from an external interface device; and

wherein the external interface device is configured to receive the adjustable blanking interval from a user and configured to transmit the adjustable blanking interval to the implantable device.

## **9. EVIDENCE APPENDIX**

None.

## **10. RELATED PROCEEDINGS APPENDIX**

None.